

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL  
PRODUCTS R&D, INC., and  
NORTON (WATERFORD) LTD.,

Plaintiffs,

v.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

Civil Action No. 24-909 (SRC)(MAH)  
(consolidated)

Civil Action No. 24-5856 (SRC)(MAH)

Civil Action No. 24-7162 (SRC)(MAH)

**PLAINTIFFS' ANSWER TO THE COUNTERCLAIMS OF  
DEFENDANTS CIPLA USA, INC. AND CIPLA LTD. IN CASE NO. 24-909**

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs"), by their attorneys, hereby reassert as if fully set forth herein each of the paragraphs of Plaintiffs' Complaint (D.I. 1) and answers the counterclaims of Defendants and Counterclaim Plaintiffs Cipla USA, Inc. and Cipla, Ltd. ("Cipla") using the paragraph numbers of Cipla's counterclaims (D.I. 14) as follows:

**The Parties**

1. On information and belief, admitted.
2. On information and belief, admitted.
3. Admitted.
4. Admitted.
5. Admitted.

6. Admitted that Norton is the holder of NDA No. 207921. Admitted that the Complaint alleged Teva was the holder of NDA No. 207921. Any remaining allegations in paragraph 6 are denied.

7. Admitted.

### **Jurisdiction and Venue**

8. The allegations in paragraph 8 purport to characterize various statutes, which speak for themselves. To the extent a response is required, admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") (collectively, the "Patents-in-Suit"). Plaintiffs do not contest subject matter jurisdiction for purposes of this action. Any remaining allegations in paragraph 8 are denied.

9. The allegations in paragraph 9 contain legal allegations to which no response is required. To the extent a response is required, Plaintiffs do not contest personal jurisdiction for purposes of this action. Any remaining allegations in paragraph 9 are denied.

10. The allegations in paragraph 10 contain legal allegations to which no response is required. To the extent a response is required, Plaintiffs do not contest venue for purposes of this action. Any remaining allegations in paragraph 10 are denied.

11. The allegations in paragraph 11 contain legal allegations to which no response is required. To the extent a response is required, admitted that Plaintiffs filed Civil Action No. 24-909 against Cipla in this judicial district on February 16, 2024 alleging infringement of the

Patents-in-Suit. Admitted that there is an actual case or controversy between Plaintiffs and Cipla regarding Cipla's liability for infringement of the Patents-in-Suit. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 11 are denied.

**The Patents-in-Suit**

12. Admitted.

13. Admitted.

14. Admitted.

15. Admitted.

16. Admitted.

17. Admitted.

18. Admitted.

19. Admitted.

20. Admitted.

21. Admitted.

22. Admitted.

23. Admitted.

24. Admitted.

25. Admitted that Plaintiffs received a letter dated January 4, 2024, from Cipla purporting to provide notice of certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Cipla's Paragraph IV Certifications") for the Patents-in-Suit with respect to Cipla's Abbreviated New Drug Application ("ANDA") No. 219000 ("Cipla's First Notice Letter"). On information and belief, admitted that Cipla's ANDA No. 219000 seeks approval from the U.S. Food and Drug Administration ("FDA") to engage in the

commercial manufacture, distribution, use, offer for sale, sale, and/or import of the product described in Cipla's ANDA No. 219000 ("Cipla's ANDA Product"). Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 25 are denied.

26. The allegations in paragraph 26 purport to characterize Cipla's First Notice Letter, which speaks for itself. To the extent a response is required, admitted that Cipla's First Notice Letter appended a document purporting to provide a detailed statement regarding Cipla's Paragraph IV Certifications for the Patents-in-Suit. Admitted that Cipla's First Notice Letter contained an offer of confidential access ("Cipla's First OCA"). Denied that Cipla's First OCA was subject to reasonable conditions. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 26 are denied.

27. Admitted.

**First Counterclaim**  
**(Declaratory Judgment of Noninfringement of the '712 Patent)**

28. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–27 above.

29. Admitted.

30. Denied.

31. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '712 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 31 are denied.

32. Denied.

**Second Counterclaim**  
**(Declaratory Judgment of Invalidity of the '712 Patent)**

33. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–32 above.

34. Denied.

35. Denied.

36. Paragraph 36 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 36 are denied.

37. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’712 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 37 are denied.

38. Denied.

**Third Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’476 Patent)**

39. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–38 above.

40. Admitted.

41. Denied.

42. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’476 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 42 are denied.

43. Denied.

**Fourth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’476 Patent)**

44. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–43 above.

45. Denied.

46. Denied.

47. Paragraph 47 makes speculative and unfounded allegations regarding Plaintiffs' future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 47 are denied.

48. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '476 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 48 are denied.

49. Denied.

**Fifth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the '509 Patent)**

50. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–49 above.

51. Admitted.

52. Denied.

53. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '509 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 53 are denied.

54. Denied.

**Sixth Counterclaim**  
**(Declaratory Judgment of Invalidity of the '509 Patent)**

55. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–54 above.

56. Denied.

57. Denied.

58. Paragraph 58 makes speculative and unfounded allegations regarding Plaintiffs' future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 58 are denied.

59. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '509 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 59 are denied.

60. Denied.

**Seventh Counterclaim**  
**(Declaratory Judgment of Noninfringement of the '510 Patent)**

61. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–60 above.

62. Admitted.

63. Denied.

64. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '510 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 64 are denied.

65. Denied.

**Eighth Counterclaim**  
**(Declaratory Judgment of Invalidity of the '510 Patent)**

66. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–65 above.

67. Denied.

68. Denied.

69. Paragraph 69 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 69 are denied.

70. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’510 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 70 are denied.

71. Denied.

**Ninth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’156 Patent)**

72. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–71 above.

73. Admitted.

74. Denied.

75. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’156 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 75 are denied.

76. Denied.

**Tenth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’156 Patent)**

77. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–76 above.

78. Denied.

79. Denied.

80. Paragraph 80 makes speculative and unfounded allegations regarding Plaintiffs' future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 80 are denied.

81. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '156 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 81 are denied.

82. Denied.

**Eleventh Counterclaim**  
**(Declaratory Judgment of Noninfringement of the '808 Patent)**

83. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–82 above.

84. Admitted.

85. Denied.

86. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla's liability for infringement of the '808 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 86 are denied.

87. Denied.

**Twelfth Counterclaim**  
**(Declaratory Judgment of Invalidity of the '808 Patent)**

88. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–87 above.

89. Denied.

90. Denied.

91. Paragraph 91 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 91 are denied.

92. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’808 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 92 are denied.

93. Denied.

**Thirteenth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’512 Patent)**

94. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–93 above.

95. Admitted.

96. Denied.

97. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’512 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 97 are denied.

98. Denied.

**Fourteenth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’512 Patent)**

99. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–98 above.

100. Denied.

101. Denied.

102. Paragraph 102 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 102 are denied.

103. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’512 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 103 are denied.

104. Denied.

**Fifteenth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’447 Patent)**

105. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–104 above.

106. Admitted.

107. Denied.

108. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’447 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 108 are denied.

109. Denied.

**Sixteenth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’447 Patent)**

110. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–109 above.

111. Denied.

112. Denied.

113. Paragraph 113 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 113 are denied.

114. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’447 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 114 are denied.

115. Denied.

**Seventeenth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’888 Patent)**

116. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–115 above.

117. Admitted.

118. Denied.

119. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’888 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 119 are denied.

120. Denied.

**Eighteenth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’888 Patent)**

121. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–120 above.

122. Denied.

123. Denied.

124. Paragraph 124 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 124 are denied.

125. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’888 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 125 are denied.

126. Denied.

**Nineteenth Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’889 Patent)**

127. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–126 above.

128. Admitted.

129. Denied.

130. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’889 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 130 are denied.

131. Denied.

**Twentieth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’889 Patent)**

132. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–131 above.

133. Denied.

134. Denied.

135. Paragraph 135 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 135 are denied.

136. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’889 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 136 are denied.

137. Denied.

**Twenty-First Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’637 Patent)**

138. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–137 above.

139. Admitted.

140. Denied.

141. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’637 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 141 are denied.

142. Denied.

**Twenty-Second Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’637 Patent)**

143. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–142 above.

144. Denied.

145. Denied.

146. Paragraph 146 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 146 are denied.

147. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’637 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 147 are denied.

148. Denied.

**Twenty-Third Counterclaim**  
**(Declaratory Judgment of Noninfringement of the ’643 Patent)**

149. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–148 above.

150. Admitted.

151. Denied.

152. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’643 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 152 are denied.

153. Denied.

**Twenty-Fourth Counterclaim**  
**(Declaratory Judgment of Invalidity of the ’643 Patent)**

154. Plaintiffs reallege and incorporate by reference each of their responses to the foregoing paragraphs 1–153 above.

155. Denied.

156. Denied.

157. Paragraph 157 makes speculative and unfounded allegations regarding Plaintiffs’ future conduct. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 157 are denied.

158. Admitted that there is an actual case or controversy between Cipla and Plaintiffs regarding Cipla’s liability for infringement of the ’643 patent. Denied that Cipla is entitled to any of the relief it seeks. Any remaining allegations in paragraph 158 are denied.

159. Denied.

#### **CIPLA’S REQUEST FOR RELIEF**

The “WHEREFORE” paragraph and subparagraphs A-G following paragraph 159 state Cipla’s Request for Relief, to which no response is required. To the extent a response is required, Plaintiffs deny that Cipla is entitled to any of the relief in the Request for Relief, or to any relief whatsoever.

#### **AFFIRMATIVE DEFENSES TO COUNTERCLAIMS**

Plaintiff affirmatively states the following defenses, undertaking the burden of proof only to the extent required by law:

##### **FIRST AFFIRMATIVE DEFENSE**

Each of Cipla’s Counterclaims fails to state a claim upon which relief can be granted. For example, Cipla has alleged no facts that, if true, would show that the Patents-in-Suit are invalid or unenforceable for any reason.

##### **SECOND AFFIRMATIVE DEFENSE**

Cipla's Counterclaims fail to state a claim upon which relief for exceptional cases under 35 U.S.C. § 285 can be granted.

### **THIRD AFFIRMATIVE DEFENSE**

Cipla is precluded under the doctrines of claim preclusion, issue preclusion, res judicata, and/or estoppel from challenging any issue decided in *Teva Branded Pharmaceutical Products R&D, Inc. et al. v. Cipla Ltd.*, No. 2:20-cv-10172 (JXN) (MAH) (D.N.J.) (Consolidated), including but not limited to the validity and/or claim construction of one or more Patents-in-Suit.

\* \* \*

Plaintiffs reserve the right to supplement and/or amend these affirmative defenses as may become available or apparent during discovery proceedings.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Cipla has infringed, will infringe, and will induce and contribute to infringement of each of the Patents-in-Suit;
- (b) A judgment that the Patents-in-Suit are valid and enforceable;
- (c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

- (d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;
- (e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;
- (f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Cipla engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and

additional period(s) of exclusivity, in accordance with 35 U.S.C.  
§ 271(e)(4)(C);

- (g) A judgment that the infringement has been willful and an enhancement of damages;
- (h) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (i) An award of Plaintiffs' costs and expenses in this action; and
- (j) Such further and other relief as this Court may deem just and proper.

Dated: July 24, 2024

WALSH PIZZI O'REILLY FALANGA LLP

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